

100 U/ml

NovoMix® 30 FlexPen®

Suspension for injection in a pre-filled pen

The active substance in NovoMix® 30 FlexPen® is insulin aspart produced biosynthetically (i.e. by use of recombinant DNA technology). NovoMix 30 contains 30% insulin aspart in a soluble fraction and 70% insulin aspart crystallised with protamine. NovoMix 30 FlexPen also contains the following other ingredients: Mannitol, Phenol, Metacresol, Zinc (as chloride), Sodium chloride, Disodium phosphate dihydrate, Protamine sulphate, Sodium hydroxide, Hydrochloric acid and Water for injections.

Produced by

Novo Nordisk A/S
DK-2880 Bagsvaerd, Denmark

What NovoMix® 30 FlexPen® is and what it is used for

NovoMix 30 FlexPen is a white suspension for subcutaneous injection in 3 ml pre-filled pens. NovoMix 30 FlexPen is an antidiabetic agent, which lowers your blood sugar after injection. When injected under your skin (subcutaneously), the onset of action will occur within 10-20 minutes of injection, the maximum effect between 1-4 hours, and the effect will last for up to 24 hours.

Therapeutic indications

NovoMix 30 FlexPen is used for the treatment of patients with diabetes mellitus (a disease where your pancreas does not produce enough insulin to control your blood sugar level). Extra insulin is therefore needed.

Before you use NovoMix® 30 FlexPen®

NovoMix 30 FlexPen should be given immediately before a meal. When necessary, NovoMix 30 FlexPen may be given soon after a meal.

If you have reduced kidney or liver function, your doctor may lower your insulin dosage. There is no clinical experience in children and adolescents under the age of 18 years.

You should not take NovoMix® 30 FlexPen® if:

- Your blood sugar is too low (hypoglycaemia). Follow the guidance for hypoglycaemia
- You are allergic to insulin aspart or any of the other ingredients contained in NovoMix 30 FlexPen.

Take special care with NovoMix® 30 FlexPen®

Never stop taking insulin if you are ill. Your need for insulin may, however, be changed. If you have an infection, fever or an operation you may need to have more insulin than usual.



If you suffer from diarrhoea, vomiting or eat less than usual you may also need less insulin than usual.

What precautions have to be taken before going abroad?

The time difference between countries may mean that you have to take your insulin and meals at different times than usual. You should therefore consult your doctor if you are planning to go abroad.

Taking NovoMix® 30 FlexPen® with food and drink

Alcohol (including beer and wine) may lead to hypoglycaemia (too low blood sugar). Therefore, be careful when you drink alcohol and never drink alcohol on an empty stomach.

Pregnancy

If you are pregnant or planning pregnancy you should see your doctor immediately to discuss your need for and type of insulin in order to control your diabetes and thereby avoid hyperglycaemia (too high blood sugar) and hypoglycaemia (too low blood sugar) as these conditions could harm your baby. There is limited clinical experience with insulin aspart in pregnancy.

Breast-feeding

Breast-feeding while you are taking insulin does not put your baby at risk. Your insulin dosage and diet may, however, need to be adjusted.

Driving and using machines

Your ability to concentrate or react may be reduced if you have hypoglycaemia. Please keep this possible problem in mind in all situations where you might put yourself and others at risk (e.g. driving a car or operating machinery). You should contact your doctor about the advisability of driving if you have:

- Frequent episodes of hypoglycaemia
- Reduced or absent warning signs of hypoglycaemia.

Using other medicines

Your insulin need may change if you take other medicines. You should therefore consult your doctor if you are currently taking any of the listed medicines or medicines which you are not sure of: Oral hypoglycaemic agents (used for the treatment of non insulin-dependent (Type 2) diabetes mellitus), monoamine oxidase (MAO) inhibitors (used for the treatment of depression), non-selective beta-blocking agents (used for the treatment of certain heart conditions and high blood pressure), angiotensin converting enzyme (ACE) inhibitors (used for the treatment of certain heart conditions, high blood pressure or elevated protein/albumin in the urine), salicylates (e.g. acetylsalicylic acid, a substance present in many medicinal products used to relieve pain and lower fever), anabolic steroids and glucocorticoids (used to treat inflammatory conditions, except topical administration), oral contraceptives (used for birth control), thiazides (used for the treatment of high

blood pressure or oedema), thyroid hormones (used for the treatment of malfunction of the thyroid gland), sympathomimetics (used for the treatment of asthma), danazol (used for the treatment of some female hormonal disorders), octreotide (used in special endocrine conditions) and sulphonamides (antibiotic). Please inform your doctor or pharmacist if you are taking or have recently taken any other medicine, even those not prescribed.

How to use NovoMix® 30 FlexPen®

To avoid the risk of passing on diseases NovoMix 30 FlexPen is for use by one person only. Do not use NovoMix 30 FlexPen if it does not appear uniformly white and cloudy after shaking. NovoMix 30 FlexPen should not be used if clumps of material are present or if solid white particles stick to the bottom or wall of the cartridges, giving a frosted appearance.

Remove air from the pen before each injection until a drop of insulin appears at the tip of the needle. Do not use NovoMix 30 FlexPen if you need to make **more** than 6 airshots before the first injection.

When you are using NovoMix 30 FlexPen, you should remove and dispose of the needle after each injection.

If you do not remove it, temperature changes may cause liquid to leak out of the needle and the concentration may change.

Take care not to drop or knock the pen.

Do not use the residual scale to measure your dose of insulin.

Do not refill NovoMix 30 FlexPen.

Do not use NovoMix 30 FlexPen in insulin pumps. If you switch from another insulin to biphasic insulin aspart, your dosage may have to be adjusted by your doctor.

How to handle this insulin

FlexPen pre-filled insulin pens should only be used in combination with products that are compatible therewith and allow the pre-filled pens to function safely and effectively.

How to take this insulin

Before injection make sure that you have got the type and strength of insulin prescribed.

NovoMix 30 FlexPen is for injection under the skin (subcutaneously). NovoMix 30 FlexPen should never be injected into a vein.

The insulin may be injected in the abdomen, thigh, upper arm or buttock. It is recommended that you eat a meal or snack containing carbohydrate within 10 minutes of the injection and measure your blood sugar level regularly. When necessary NovoMix 30 FlexPen may be given soon after a meal.

If you use more NovoMix® 30 FlexPen® than you should

If you take too much insulin, miss a meal or exercise more than usual, your blood sugar may become too low (i.e. hypoglycaemia).

The first **symptoms of hypoglycaemia** can come on suddenly. They may include: cold sweats, cool pale skin, fatigue, nervousness or tremor, anxious feeling, unusual tiredness and weakness,

confusion, difficulty in concentration, drowsiness, excessive hunger, temporary vision changes, headache, nausea and palpitation.

What to do in case of hypoglycaemia?

If you experience any of the symptoms mentioned above, you should immediately take sugar or a sugar containing product. So always carry sugar lumps, sweets, biscuits or fruit juice with you. Tell your relatives, friends and close colleagues that you have diabetes and how they can help you if you get a severe hypoglycaemic reaction. They must know that they should not give you anything to eat or drink if you are unconscious as you could choke.

If you are unconscious, you should be turned on your side and your relatives, friends or colleagues should get medical help immediately. You may recover from unconsciousness more quickly if you are given an injection of the hormone glucagon by a person who has been instructed in how to use it. If glucagon is injected, you should also be given sugar, a product containing sugar or glucose by mouth as soon as you are conscious again. If you do not respond to glucagon treatment, you will have to be treated in a hospital.

See your doctor if you have had repeated hypoglycaemic reactions or one reaction that led to unconsciousness, as your insulin dose may need to be changed.

If severe hypoglycaemia is not treated, it can cause temporary or permanent brain damage, and death.

If you use less NovoMix® 30 FlexPen® than you should

If you are ill with fever or if you eat much more than usual and repeatedly take less insulin than you need, your blood sugar may become unusually high (i.e. result in hyperglycaemia).

The **symptoms of unusually high blood sugar levels** will appear gradually. They include: increased urination, thirst, loss of appetite, nausea, vomiting, drowsiness (fatigue), flushed dry skin, dry mouth, acetone breath.

What to do in case of hyperglycaemia?

If you recognise any of the symptoms mentioned above, you should test your blood sugar level and your urine for ketones as soon as possible as the symptoms may indicate that you have a condition called ketoacidosis. This condition is critical and if untreated may result in diabetic coma and death. You should therefore seek medical advice immediately and possibly take some extra insulin.

Possible side effects

Like all medicines, NovoMix 30 FlexPen can have side effects.

NovoMix 30 FlexPen may cause **hypoglycaemia** of which the symptoms have been mentioned above. Redness, swelling and itching at the site of injection (also called **local allergic reactions**) may be experienced by some people. Usually these symptoms disappear within a few weeks during continued use.

If the symptoms do not disappear, spread to other parts of your body or if you suddenly feel sick (i.e. if you sweat, vomit, have difficulties in breathing, have rapid heart beat, feel dizzy),

you should consult your doctor immediately as these reactions may be due to **systemic allergic reactions** which are rare but may be serious.

Your skin may thicken or pit if the injection site is not rotated.

When you first start your insulin treatment you may suffer from visual disturbances or swelling of the extremities.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Storing NovoMix® 30 FlexPen®

Store NovoMix 30 FlexPen which you are **not using** at 2°C - 8°C in a refrigerator (not too near the freezer compartment). Do not freeze.


NovoMix 30 FlexPen that **you are using** must not be kept in a refrigerator. NovoMix 30 FlexPen can be used or carried with you as a spare for up to 4 weeks (not above 30°C), after which it must be discarded.

In order to protect from light keep the cap on when NovoMix 30 FlexPen is not in use.

Keep out of the reach and sight of children.

Do not use after the expiry date stated on the label and carton.

Do not use NovoMix 30 FlexPen if it does not appear uniformly white and cloudy after shaking.

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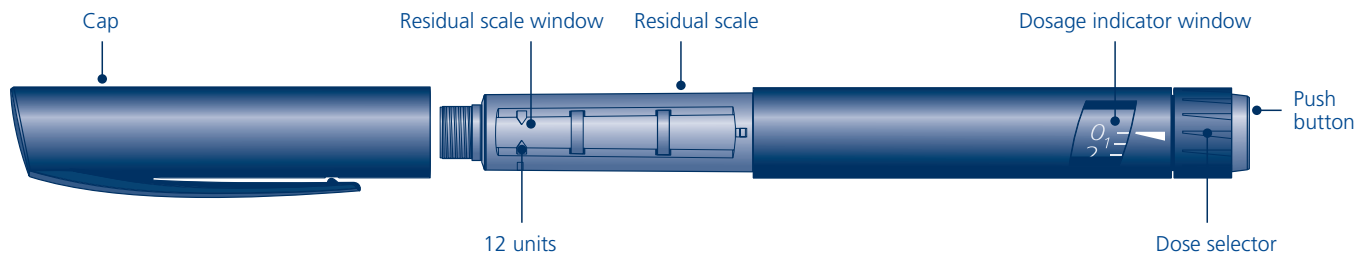
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NovoMix® 30 FlexPen®

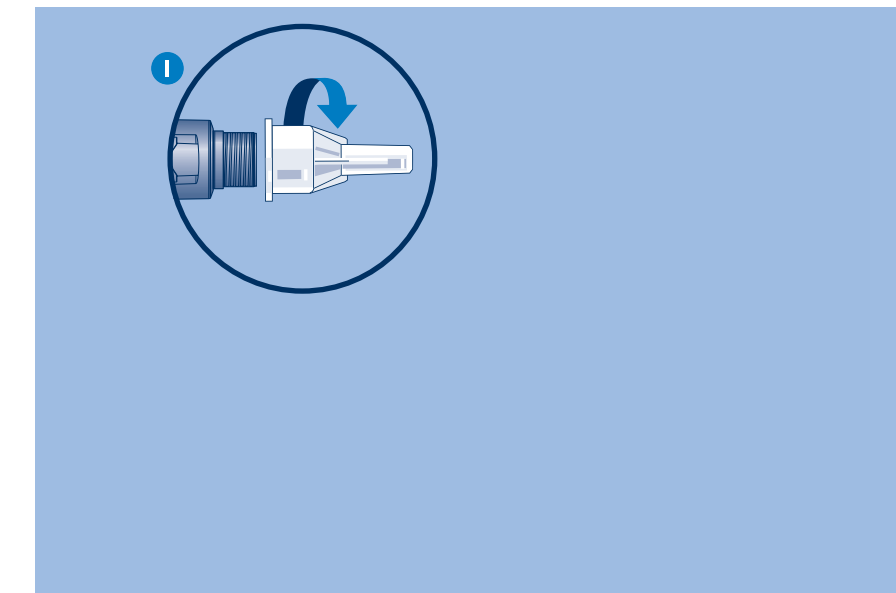
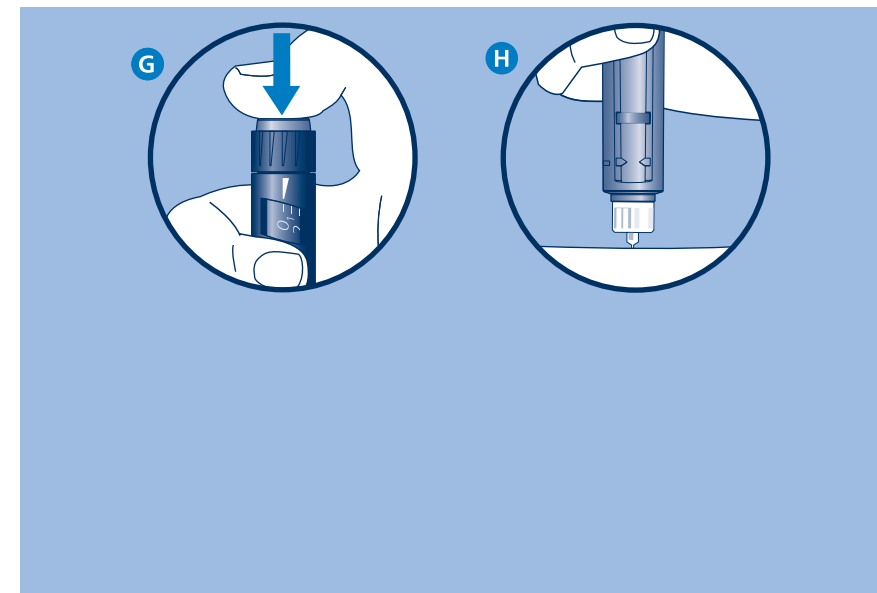
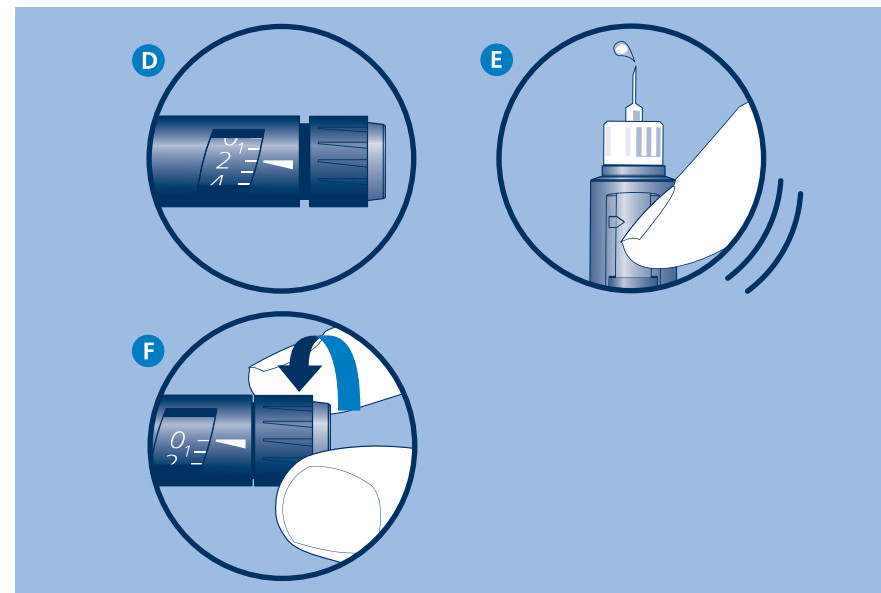
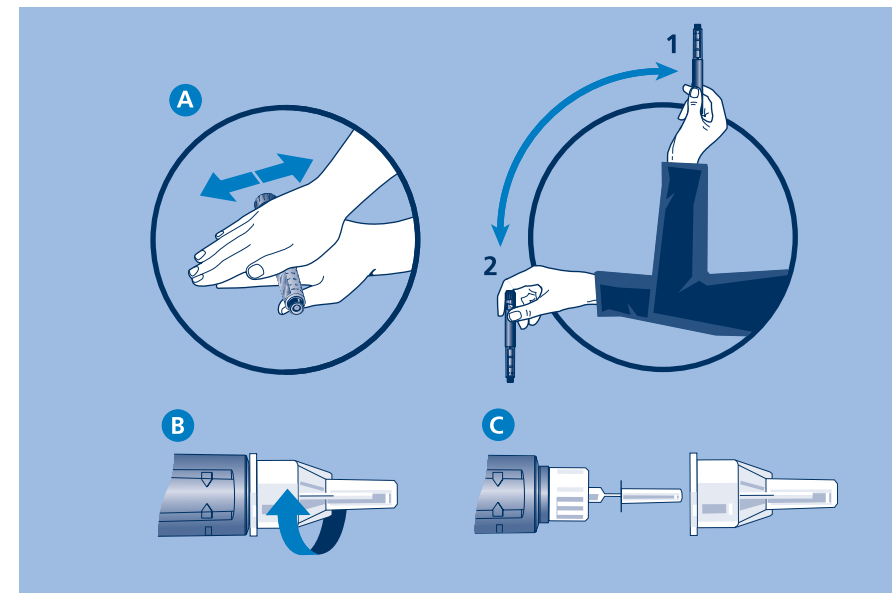
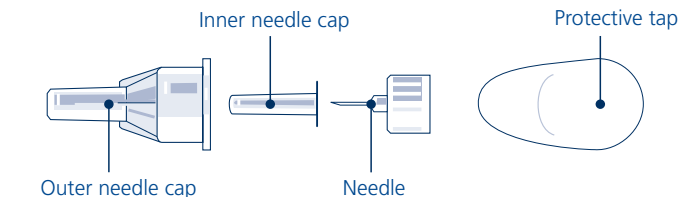
Introduction

NovoMix® 30 FlexPen® is a unique dial-a-dose insulin pen. You can dial doses from 1 to 60 units in increments of 1 unit. NovoFine® **S** needles of 8 mm or shorter in length are designed to be used with FlexPen. Look for an **S** on the needle box. The **S** stands for shortcap.

Please read the following instructions carefully before using your NovoMix® 30 FlexPen®.



NovoFine® **S**



Getting started

Check that your NovoMix 30 FlexPen contains the correct type of insulin.

Take off the cap.

A Before using NovoMix 30 FlexPen the first time: Roll NovoMix 30 FlexPen between your palms 10 times. Thereafter turn the pen up and down between position **1** and **2** 10 times so that the glass ball moves from one end of the reservoir to the other. The rolling and turning procedure must be repeated at least once more until the liquid appears uniformly white and cloudy. Inject immediately.

Before each injection: Turn NovoMix 30 FlexPen up and down between position **1** and **2** 10 times so that the glass ball moves from one end of the reservoir to the other. The turning procedure must be performed until the liquid appears uniformly white and cloudy. Inject immediately.

To ensure even mixing there must be at least 12 units of insulin left in the reservoir. If there are less than 12 units left, do not use NovoMix 30 FlexPen.

B Remove the protective tab from a NovoFine **S** short cap needle and screw the needle tightly onto NovoMix 30 FlexPen.

C Pull off the outer and inner needle caps. Do not discard the outer needle cap.

Priming NovoMix® 30 FlexPen® prior to each injection

Small amounts of air may collect in the needle and reservoir during normal use.

To avoid injection of air and ensure proper dosing:

D Dial 2 units.

E Hold NovoMix 30 FlexPen with the needle pointing upwards and tap the reservoir gently with your finger a few times. Holding NovoMix 30 FlexPen with the needle upwards, press the push button all the way in. A drop of insulin should appear at the needle tip. If not, repeat the procedure no more than 6 times.

If a drop of insulin still does not appear, the device is defective, and must not be used.

Setting the dose

F Check that the dose selector is set at zero. Dial the number of units you need to inject.

The dose can be corrected either up or down by turning the dose selector in either direction. When dialing back be careful not to push the push button as insulin will come out. You cannot set a dose larger than the number of units left in the reservoir.

Making the injection

Use the injection technique advised by your doctor.

G Deliver the dose by pressing the push button all the way in. Be careful only to push the push button when injecting.

H After the injection the needle should remain under the skin for at least 6 seconds. Keep the push button fully depressed until the needle is withdrawn from the skin. This will ensure that the full dose has been delivered.

Removing the needle

I Replace the outer needle cap and unscrew the needle. Dispose of it carefully.

It is important that you use a new needle for each injection. Health care professionals, relatives and other carers should follow general precautionary measures for removal and disposal of needles to eliminate the risk of unintended needle penetration.

Dispose of the used NovoMix 30 FlexPen carefully without the needle attached.

Maintenance

Your NovoMix 30 FlexPen is designed to work accurately and safely. It should be handled with care. Avoid situations where NovoMix 30 FlexPen might be damaged.

You can clean the exterior of your NovoMix 30 FlexPen by wiping it with cotton wool moistened with alcohol. Do not soak it in alcohol or wash or lubricate it as this may damage the mechanism.